UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,369	02/29/2000	Paul B. Fisher	0575/56778/JPW/JML	1885

7590 09/10/2002

John P White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
CHEN, LIPING	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/10/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/515,369	FISHER ET AL.	
	Examiner	Art Unit	
	Liping Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Liping Chen of Group Art Unit 1632.

Status of the claims

A restriction was made on 06/18/2002. Applicant's election without traverse of Group I, claims 1-9 and 14-20 as *in vitro* method, in Paper No. 17, is acknowledged. Claims 10-13 and 21-25 are withdrawn as being directed to a non-elected invention.

Claims 1-25 are pending and claims 1-9 and 14-20 are examined in this office action only according to the election. Claims 8, 9 and 14-19 are examined in part as they contain subject matter which reads on an *in vivo* method or a host cell in an *in vivo* environment.

Priority

This application is filed on 02/29/2000.

Objection

The disclosure is objected to because of the following informalities:

Claims 8, 9 and 14-19, are objected to because they encompass more than the elected invention, specifically they state "a host cell", it reads on *in vivo*. It is suggested this be written "an isolated host cell".

Claim 19 also states "topical application". It only reads on *in vivo*. It is suggested this be removed.

The label "0" between "-81" and "+45" in Fig. 6 is incorrect. It is suggested this be written to "-1".

Page 10, line 21, states "thymidine (T) at position –2241 to the cytosine (C) at position 0". It is suggested this be written to state "thymidine (T) at position -2241 to the cytosine (C) at position -1".

Page 13, line 29-33, states "the promoter having about 2241 base pairs" and "beginning with (T) thymidine at nucleotide position –2241 and ending with (C) cytosine at nucleotide position 0". It is suggested this be written to state "the promoter having about 2240 base pairs" and "beginning with (T) thymidine at nucleotide position –2241 and ending with (C) cytosine at nucleotide position –1, which correspondence to the position of 1 to 2240 of SEQ ID NO:1".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-9, 15, 16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 16 and 20 as written are indefinite as using the term of "functionally equivalent to" a nucleotide sequence or a promoter sequence. Although there is definition in the specification for the "functionally equivalent" (specification, page 16, line 1-8), the words, "substantially similar", used in the definition does not give any concrete limitation. The depending claims 3, and 6-9 are rejected to for being dependent on indefinite claim 1.

Claims 1 and 20, as written are indefinite as using the term of "under stringent conditions". There is no definition as to which conditions are "stringent conditions". The depending claims 3 and 6-9 are rejected to for being dependent on indefinite claim 1.

Claims 5, 15, 16 and 20, as written are indefinite as using the term of "from the tymidine at position –2241 to the cytosine at position 0 " of SEQ ID NO:1. There is no negative position in SEQ ID NO:1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 6-9, 14, 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. In the instant case, while a written description for Mda-7 promoter having about 2241 base pairs derived from the 5' flanking region of the Mda-7 gene as shown in SEQ ID NO:1 (specification, page 13, line 29 to page 15, line 16) is generally understood, there is no written description regarding to how to define a sequence is "functionally equivalent" to a Mda-7 promoter by sequence analysis. Although the specification gives a definition for "functionally equivalent" to Mda-7 as one which is capable of directing transcription of a downstream coding sequence in substantially similar time frames of expression and in substantially similar amounts and with substantially similar tissue specificity as the Mda-7 promoter (specification, page

16, line 1-8). This definition does not provide any description as the time range been the substantially similar time frame, the limitation for a promoter having substantially similar tissue specificity, and the amounts of gene expression is considered as substantially similar amounts. Nor is there any structurally similar boundaries set forth. Therefore, a skilled artisan cannot envision all promoters claimed. Further, the specification does not provide written description regarding what is the stringent conditions for detecting a promoter which comprises a nucleotide sequence that hybridizes to a sequence complementary to Mda-7 promoter or its functionally equivalent, no written description regarding the length and the percentage of homology of the nucleotide to Mda-7 promoter, which will be obtained under the stringent condition. Therefore, with the exception of the SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of any promoter that is "functionally equivalent" to Mda-7 promoter or that comprises a nucleotide sequence that hybridized to Mda-7 under stringent conditions even reduction to practice has occurred, regardless of the complexity or simplicity of the method used, nor an Mda-7 promoter from other species. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the

invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.,* 48 USPQ2d 1641, 1646 (1998).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In the instant case, only Mda-7 promoter and SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims1, 3, 6-9, 14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Deiry et al. (Cell 75:817-825, 1003) in view of Jiang et al. (Oncogene 10:1855-64, 1995).

Claims 1 and 20 are directed to an isolated Mda-7 promoter capable of directing transcription of a heterologous coding sequence positioned downstream therefrom, the promoter comprising a nucleotide sequence functionally equivalent to the nucleotide sequence shown in SEQ ID NO:1; claims 3, 6 and 7 are directed to an expression construct containing the promoter and a heterologous coding sequence; claims 8 and 9 are directed to a cell containing the expression construct; claims 14 and 17-19 are directed to a method for expressing foreign DNA using the expression construct.

El-Deiry et al. teaches WAF1 promoter construct WWP-Luc activated expression of luciferase only in the presence of wild-type p53 (El-Deiry, page 822, sec. parag. and Fig. 6). El-Deiry et al. does not teach that WAF1 promoter is a promoter directing a gene differentially expressed in human melanoma cells.

Jiang et al. Teaches mad-6 is identical to WAF1 that encodes the (M)r 21,000 protein (p21) that is an inhibitor of cyclin-dependent kinases. Jiang et al. further teaches that induction of growth arrest and terminal differentiation in H0-1 human melanoma cells by recombinant human fibroblast interferon (IFN-beta) and the antileukemic compound mezerein (MEZ) results in a increase in p21 levels (Jiang, Abstract). The p21 expression is controlled under a promoter, p21 promoter, that is

functionally equivalent to Mda-7 promoter of the instant invention with the substantial similar amounts, substantial similar time frame and substantial similar tissues, which is confirmed in the instant invention Figure 4.

Since the WAF1 promoter taught by El-Deiry et al. is p21 promoter taught by Jiang et al, which is regulated equivalent to the nucleotide sequence shown in SEQ ID NO:1, and is capable of directing transcription of a heterologous coding sequence encoding luciferase, the promoter of El-Deiry et al. possesses all elements of the instant invention regardless the preamble, which does not have patentable weight in art rejection. Thus, El-Deiry et al. clearly anticipates the claimed invention.

Conclusion

No claim is allowed.

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable,

inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Liping Chen, Ph.D.
Patent Examiner
Group 1632

Deborah Reynolds

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600